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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,897	06/30/2001	Elazar Rabani	Enz-60	1538

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ENZO BIOCHEM, INC.
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EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 03/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/896,897

Applicant(s)

RABANI ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40,953 and 954 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-40 and 953 and 954 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The applicant's response filed 10/29/2004 to the Office action has been entered. Claims 1-40 and 953-954 are pending.

1. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because of the amendment.

2 The rejection of claims 1-4, 7, 11, 13-15, 17-24, 27, 33-35, and 37 under 35 U.S.C. 102(e) as being anticipated by Li (6,696,256) is withdrawn because of the amendment.

3. The rejection of claims 5-6, 8-10, 12, 16, 25-26, 28-32, and 36-40 under 35 U.S.C. 103(a) as being unpatentable over Li (6,696,256) as applied to claims 1-4, 7, 11, 13-15, 17-24, 27, 33-35 and 37 above, and further in view of Kool et al. (6,479,650, issued November 12, 2002) is withdrawn because of the amendment.

NEW GROUNDS REJECTIONS AS NECESSITATED BY THE AMENDMENT

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an

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international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-4, 7, 9-15, 17-24, 27, 29-35, 37-40 and 953-954 are rejected under 35 U.S.C. 102(e) as being anticipated by Lizardi et al. (6,261,782, issued July 17, 2001).

Lizardi et al. disclose a composition matter that comprises a library of nucleic acid analytes (See column 4, lines 4-11 and See column 61 to column 62, example 1, and column 63 to 64, example 2) and an array of nucleic acids (See column 4, lines 19-20)

Wherein said library comprises diverse nucleic acid analytes, which comprises

(i) an inherent universal detection target (UDT) or non inherent universal detection target comprising at least one conserved sequence present in the diverse nucleic acid analytes (See column 7, lines 1-7, where when a single restriction enzyme is used, then a conserved sequence is generated, and also see column 50, lines 30-66 where FokI cleavage at the DNA results a conserved sequence GGATG sequence ligated to the adapter-indexer, further see column 12, lines 11-13, where a common identical sequence is present in the adapter-indexer),

(ii) a universal detection element (UDE), said UDE being attached to the UDT, said nucleic acid analytes being hybridized to said array of nucleic acids, and said array of nucleic acid being fixed or immobilized to a solid support (See column 4, lines 1-11, column 15, lines 6-48, column 53, lines 23-36),

wherein said UDE generates a signal indicating the presence or quantity of said diverse nucleic acid analytes by means of said attachment of said UDE to said UDT (See column 17, lines 2-15, column 54, lines 28-34 and column 103, lines 6-9).

With regard to claims 2-3, 13-15, 22-24 and 953-954, Lizardi et al disclose that the nucleic acid samples used in the method are genomic sample, mRNA sample, cDNA sample, nucleic acid libraries, whole cell samples, and tissue samples (See column 8, lines 54-59). Preferred nucleic acid samples used in the method are genomic samples and mRNA samples (See column 8, lines 62-64). Since the terms, for example, secondary structure, splicing elements used in the claims do not have specific sequence, any sequence used in the method reads on these limitations).

With regard to claims 4, 11, 31, and 35, Lizardi et al. disclose that the detector probes immobilized in an array (See column 4, lines 19-20) are oligonucleotides (See column 14, lines 46-48).

With regard to claims 12 and 32, Lizardi et al. disclose that oligonucleotide probe was covalently attached to the surface of a glass-slide via a poly-enthylene-glycol spacer moiety (See column 63, lines 64-66). The spacer moiety is interpreted as a chemical linker or linkage arm.

With regard to claims 7, 9-10, 27, and 29-30, Lizardi et al. disclose that solid-state substrate for use in probe array can be glass (See column 15, lines 55-67).

With regard to claims 17 and 37, Lizardi et al. disclose that the ligator-detector is detected directly or indirectly in which the pattern of ligator-detectors coupled to different detector probes indicates the nucleic acid analytes in the sample (See column 103, lines 6-9).

With regard to claims 18-21 and 38-40, Lizardi et al. disclose that the labels are fluorescent molecules, enzymes, antibodies and ligands (See column 17, lines 11-15).

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With regard to claims 33-34, Lizardi et al. disclose adapter-indexer corresponding to UDT comprises homopolymeric sequence or heteropolymeric sequence (See fig 5, panel C and column 6, lines 2-5).

Based upon the analysis above, the teachings of Lizardi et al. anticipate the limitations of the claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 5-6, 8, 16, 25-26, 28 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lizardi et al. (6,261,782, issued July 17, 2001) as applied to claims 1-5, 7, 9-15, 17-25, 27, 29-40 and 953-954 above, and further in view of Egholm et al. (6,451,588, issued September 17, 2002)

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The teachings of Lizardi are set forth in section 5 above. Lizardi et al. do not disclose modified sugar or phosphate or base moieties, and polyacrylamid used as porous solid support.

With regard to claims 6, and 26, Egholm et al. disclose nucleic acid analog through modifications of the sugar and the nucleobase (See column 4, lines 59-67 and column 5, lines 26-35).

With regard to claims 5, 16, 25 and 36, Egholm et al. disclose high-affinity nucleic acid analog which includes PNA (See column 5, lines 26-30).

With regard to claims 8 and 28, Egholm et al. disclose that the solid support immobilized the probes may be polyacrylamide (See column 15, lines 43-50).

One of ordinary skill in the art would have been motivated to apply the modification to the sugar, or base of the nucleic acid probe in the array of Lizardi et al. The motivation is that the nucleic acid analog as taught by Egholm et al. attains desired properties, for example, optimized hybridization specificity or affinity, chemical stability (See column 4, lines 67 to column 5, line 1-9) and higher affinity for a strand of DNA than the corresponding complementary strand of DNA (See column 5, lines 26-30). In addition, the method of Egholm et al. for hybridization of a collection of probes to a target nucleic acid is an improvement of nucleic acid analysis in an array (See column 1, lines 59-61 and column 16 lines 1-22) in that the detection can be accomplished following gel electrophoresis (See column 15, lines 61-67. Thus t would have been prima facie obvious to apply the modification to the sugar, or the base and solid support made from polyacrylamide to make the composition comprising the library of analytes, and array of nucleic acid fixed on a solid support and the analytes comprise UDT and UDE.

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6. The references 0104620 and 0104460 lined through in PTO-1449 filed 1/7/04 were not found in the response.

Summary

7. No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

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Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung *J.T.*
February 2, 2005


JEFFREY FREDMAN
PRIMARY EXAMINER
2/23/05